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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,546	12/05/2003	Charles C. Raney	7404-541	1896

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EXAMINER	
DRYDEN, MATTHEW DUTTON	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 07/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/729,546	RANEY ET AL.	
	Examiner	Art Unit	
	Matthew D. Dryden	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/2003, 5/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abbott Laboratories (WO 98/24366) in view of Terumo (WO 00/40150). Abbott Laboratories disclose the claimed invention except for the test strip comprising a sampling passageway located between the top and bottom surface. Abbott Laboratories does disclose a test strip (combination of elements 1100 and 1126 in Figure 29A) comprising a body having a first end and a second end (see around element 1100 in Figure 21A), a top surface (around element 1114 in Figure 21A), a bottom surface (around element 1112 in Figure 21A, or around element 1128 in Figure 29A and element 3002 in Figure 32), and an aperture between the first and second ends and extending from the top surface to the bottom surface (see around elements 1116 and 1104 in Figure 21A), and a sealing member on the bottom surface (see element 3000 in Figure 32). Terumo teaches it is known to provide a fluid passageway (see element 33 in Figure 13) between the top and bottom surfaces of the test strip that includes an inlet opening communicating with an aperture (see around elements 32 and 39a for the apertures) to transfer the blood to an area of the strip for analysis (see page 19, lines

19-29). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Abbott Laboratories with a test strip comprising a sampling passageway, as taught by Terumo, to transfer the blood to an area of the strip for analysis.

Regarding claim 2, see Page 34, lines 26-31 of Abbott Laboratories.

Regarding claim 3, the sealing member as discussed above is capable of deforming upon pressing against the skin.

Regarding claim 4, see around element 3010 in Figure 32.

Regarding claims 5 and 6, the recessed surface can be viewed as extending at an obtuse angle from the bottom surface to the inlet opening (see around elements 3010, c, b, and d in Figure 32), and can also be viewed as being in the range of 100-150 degrees.

Regarding claim 7, Abbott Laboratories disclose the claimed invention except for the test strip comprising a sampling passageway located between the top and bottom surface and the passageway having an inlet opening communicating with the end edge at a location spaced from the bottom surface. Terumo teaches to provide a test strip (a combination of elements 32a and 3a in Figure 4) with a passageway that has an inlet that communicates with an end edge and that is spaced from the bottom surface (see around element 33a in Figure 4) to transfer the blood from the incision to an area of the strip for analysis. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Abbott Laboratories with a sampling passageway located between the top and bottom surface and the

passageway having an inlet opening communicating with the end edge at a location spaced from the bottom surface, as taught by Terumo, to transfer the blood from the incision to an area of the strip for analysis.

Regarding claim 8, the system as modified discloses the claimed invention except for the device comprising a sealing member that extends from a first side edge to a second side edge. It would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the device of Abbott Laboratories with a sealing member that extends from a first side edge to a second side edge to seal the entire strip on the skin of the user to prevent blood or bodily fluid from oozing around the exterior of the device, which in turn reduces the chance of contamination or possible harm to the user.

Regarding claim 9, see Page 34, lines 26-31 of Abbott Laboratories.

Regarding claim 10, the sealing member as discussed above is capable of deforming upon pressing against the skin.

Regarding claim 11, see around element 3010 in Figure 32.

Regarding claims 12 and 13, the recessed surface can be viewed as extending at an obtuse angle from the bottom surface to the inlet opening (see around elements 3010, c, b, and d in Figure 32), and can also be viewed as being in the range of 100-150 degrees.

Regarding claim 14, the system as modified discloses the claimed invention see rejection of claims 1 and 4 above.

Regarding claims 15 and 16, the recessed surface can be viewed as extending at an obtuse angle from the bottom surface to the inlet opening (see around elements 3010, c, b, and d in Figure 32), and can also be viewed as being in the range of 100-150 degrees.

Regarding claim 17, the inlet opening as modified is spaced from the top surface.

Regarding claim 18, Abbott Laboratories disclose the claimed invention except for the test strip comprising a sampling passageway communicating with at least one of the end edge and the recessed surface. Regarding the recessed surface of the test strip see rejection of claim 4 above. Terumo teaches to provide a test strip (a combination of elements 32a and 3a in Figure 4) with a passageway that has an inlet that communicates with an end edge (see around element 33a in Figure 4) to transfer the blood from the incision to an area of the strip for analysis. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Abbott Laboratories with a sampling passageway having an inlet opening communicating with the end edge at a location spaced from the bottom surface, as taught by Terumo, to transfer the blood from the incision to an area of the strip for analysis.

Regarding claims 19 and 20, the recessed surface can be viewed as extending at an obtuse angle from the bottom surface to the inlet opening (see around elements 3010, c, b, and d in Figure 32), and can also be viewed as being in the range of 100-150 degrees.

Regarding claim 21, see Page 34, lines 26-31 of Abbott Laboratories.

Regarding claim 22, a sealing member on the bottom surface aligned with the inlet opening and positioned to contact and seal with the skin when said body is pressed against the skin (see element 3000 in Figure 32).

Regarding claim 23, the system as modified discloses the claimed invention except for the device comprising a sealing member that extends from a first side edge to a second side edge. It would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the device of Abbott Laboratories with a sealing member that extends from a first side edge to a second side edge to seal the entire strip on the skin of the user to prevent blood or bodily fluid from oozing around the exterior of the device, which in turn reduces the chance of contamination or possible harm to the user.

Regarding claim 24, Abbott Laboratories disclose the claimed invention except for the device comprising a sampling passageway including an inlet opening communicating with a sampling surface at a location spaced from the bottom surface. Regarding the hydrophobicity of the surface see page 34 lines 26-31. Terumo teaches to provide a test strip (a combination of elements 32a and 3a in Figure 4) with a passageway that has an inlet that communicates with an end edge (see around element 33a in Figure 4) and a sampling surface (see around element 34 in Figure 4) to transfer the blood from the incision to an area of the strip for analysis. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Abbott Laboratories with a sampling passageway having an inlet opening communicating with a sampling surface at a location spaced from the bottom

surface, as taught by Terumo, to transfer the blood from the incision to an area of the strip for analysis.

Regarding claim 25, Abbott Laboratories disclose an aperture between the first and second ends and extending from the top surface to the bottom surface (see around elements 1116 and 1104 in Figure 21A, also see around elements 3012 in Figure 32).

Regarding claim 26, Abbott Laboratories discloses the claimed method of placing adjacent to the incision a test strip (a combination of elements 1100 and 1126 in Figure 29C), the test strip has a body having a first end and a second end (one end can be seen above element 1116 in Figure 23 and the second end can be seen below element 1114 in Figure 23), a top surface (around element 114 in Figure 21A), a bottom surface (around element 3001 in Figure 32), an aperture between the first and second ends and extending from the top surface to the bottom surface (see around elements 116 and 1104 in Figure 21A, and around elements 3012 in Figure 32), and a sealing member on the bottom surface (see around element 3002 in Figure 32 and around element 1128 in Figure 29A). However, Abbott Laboratories does not disclose the claimed sampling passageway located between the top and bottom surface and an inlet of the passageway communicating with the aperture. Terumo teaches it is known to provide a fluid passageway between the top and bottom surfaces of the test strip that includes an inlet opening communicating with an aperture (see around elements 32 and 39a for the apertures) to transfer the blood to an area of the strip for analysis (see element 33 in Figure 13 and see page 19, lines 19-29). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Abbott

Laboratories with a test strip comprising a sampling passageway, as taught by Terumo, to transfer the blood to an area of the strip for analysis.

Also, Abbott Laboratories teaches it is known to maintain the test strip in position against the skin to draw enough fluid into the strip portion (see page 44, lines 1-9), so when modified by Terumo to include the sample passageway the method would read on this portion of the claim.

Regarding claim 27, Abbott Laboratories discloses the claimed method of placing adjacent to the incision a test strip (a combination of elements 1100 and 1126 in Figure 29C), the test strip has a body having a first end and a second end (one end can be seen above element 1116 in Figure 23 and the second end can be seen below element 1114 in Figure 23), a top surface (around element 114 in Figure 21A), a bottom surface (around element 3001 in Figure 32), an aperture between the first and second ends and extending from the top surface to the bottom surface (see around elements 116 and 1104 in Figure 21A, and around elements 3012 in Figure 32), and a sealing member on the bottom surface (see around element 3002 in Figure 32 and around element 1128 in Figure 29A). However, Abbott Laboratories does not disclose the claimed sampling passageway including an inlet opening communicating with the end edge at a location spaced from the bottom surface. Terumo teaches to provide a test strip (a combination of elements 32a and 3a in Figure 4) with a passageway that has an inlet that communicates with an end edge and that is spaced from the bottom surface (see around element 33a in Figure 4) to transfer the blood from the incision to an area of the strip for analysis. It would have been obvious to one having ordinary skill in the art at the

time the invention was made to modify the device of Abbott Laboratories with a sampling passageway located between the top and bottom surface and the passageway having an inlet opening communicating with the end edge at a location spaced from the bottom surface, as taught by Terumo, to transfer the blood from the incision to an area of the strip for analysis.

Also, Abbott Laboratories teaches it is known to maintain the test strip in position against the skin to draw enough fluid into the strip portion (see page 44, lines 1-9), so when modified by Terumo to include the sample passageway the method would read on this portion of the claim.

Regarding claim 28, see rejection of claim 26 above and for the recessed surface extending between the inlet opening and the bottom surface see around element 3010 in Figure 32, of Abbott Laboratories.

Regarding claim 29, see the rejection of claim 27 above, because the claim recites the limitation of the inlet opening communicating with at least one of the end edge and for the recessed surface see rejection of claim 28 above.

Regarding claim 30, Abbott Laboratories disclose the claimed method except for the device comprising a sampling passageway including an inlet opening communicating with a sampling surface at a location spaced from the bottom surface. Regarding the hydrophobicity of the surface see page 34 lines 26-31. For the structural contents of Abbott Laboratories see the rejection of all the previous method claims, and for the portion of the bottom surface adjacent to the sampling surface being hydrophobic see Page 34, lines 26-31. Terumo teaches to provide a test strip (a combination of

elements 32a and 3a in Figure 4) with a passageway that has an inlet that communicates with an end edge (see around element 33a in Figure 4) and a sampling surface (see around element 34 in Figure 4) to transfer the blood from the incision to an area of the strip for analysis. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Abbott Laboratories with a sampling passageway having an inlet opening communicating with a sampling surface at a location spaced from the bottom surface, as taught by Terumo, to transfer the blood from the incision to an area of the strip for analysis.

Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent Application Publication 2002/0099308 Bojan et al disclose a fluid collection and monitoring device

U.S. Patent Application Publication 2002/0177761 Orloff et al disclose an integrated lancing and analytic device

U.S. Patent 6,093,156 Cunningham et al disclose a method and apparatus for obtaining blood for diagnostic tests.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew D. Dryden whose telephone number is (571) 272-6266. The examiner can normally be reached on Monday-Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MDD

MAX F. HINDENBURG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

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3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.